

Process for Addressing OIR Non-Compliance with NIH Policy for Results Reporting for ClinicalTrials.gov

-90 days before results are due, Office of Protocol Services (OPS) sends notification to the NIH intramural investigator / Responsible Party (RP) of requirement for results reporting by completion date and transfers ownership to RP, IC Contact* (POC) copied



-30 days before the due date, OPS sends a reminder to the RP of the requirement for results reporting by completion date (POC copied)



At **one year+1 day** OPS notifies the RP that results have not been submitted; and if not submitted in 30 days will notify the OIR Compliance Officer (POC)



At **+30 days**, OPS notifies the OIR Compliance Officer who notifies the Clinical Director (CD), the POC and copies the Scientific Director (SD), and IC director to warn the RP that research support and clinical privileges are in jeopardy



At **+60 days** the Deputy Director Intramural Research (DDIR) sends an official notice of non-compliance to the RP, IC director, CD and SD that “failure to comply will lead to suspension of research support and suspension of clinical privileges”
Board of Scientific Counselors (BSC) notified in next review of RPs failure to comply



At **+90 days**, DDIR and IC initiate steps to suspend research support and clinical privileges of the RP
Failure to comply may also trigger personnel action.
If other IC investigators are also failing to comply, steps may be taken to suspend the clinical research privileges of the IC Director and the CD



Responsible Party's research activity is suspended

National Library of Medicine posts notice of non-compliance on ClinicalTrial.gov record

If subject to Title VIII and NIH policy

If Subject to NIH policy

NIH notified FDA of suspension of clinical research activities.

FDA may issue a notice of non-compliance; After 30 days, FDA may initiate additional enforcement actions